

### **DISCUSSION OF THE AMENDMENTS AND REMARKS**

Claims 1-22 are pending.

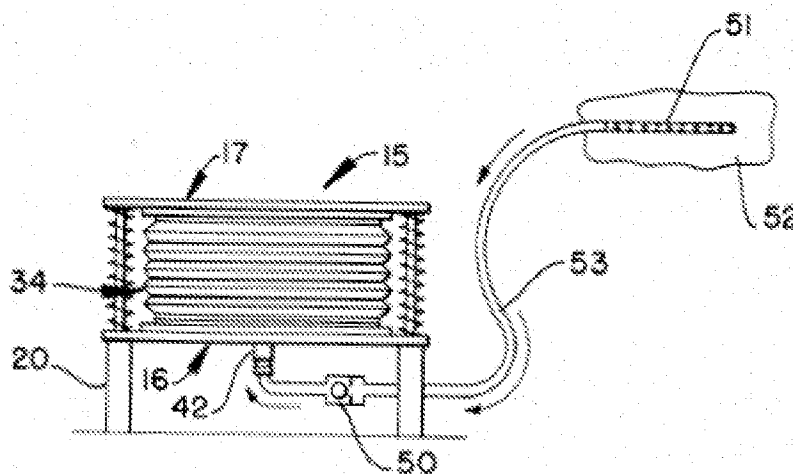
Claim 24 is added. Support for new claim 24 is found at page 5, lines 12-17.

No new matter is believed to be added upon entry of the amendment whereby claims 1-22 and 24 will be active.

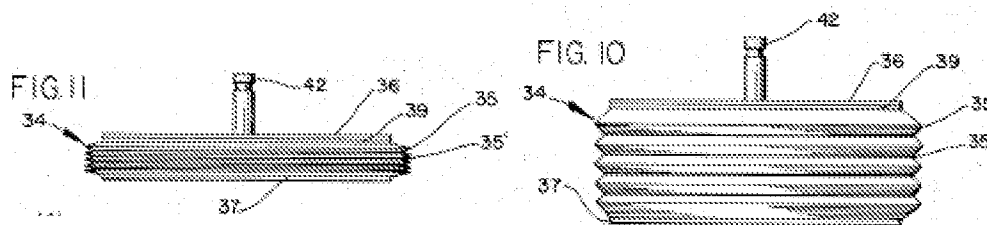
The Office has taken the position that the claimed closed drainage device is unpatentable under 35 U.S.C. § 103(a) over Lewis, Jr. (US 3,809,087) (hereafter "Lewis") in view of Broadnax, Jr. (US 5,067,950) (hereafter "Broadnax"), and in further view of any one of Gilcher *et al.* (US 4,385,630), Olaussen (US 6,113,568), Hogan (US 4,820,282), Dennehey (US 4,294,250), Friend (US 3,982,546), and Trace (US 2,936,757).

Applicant respectfully traverses these rejections because the disclosure of Lewis (either alone or in combination with any one of the secondary references) does not disclose or suggest a pre-evacuated chamber and the mode of operation of Lewis is incompatible with the claimed closed drainage device. Applicant believes that the issues can be consolidated and dismissed upon consideration of Lewis' mode of action.

Lewis discloses a continuous suction apparatus for post operative wounds that includes a device that contains a bellows-mechanical structure and a "collapsible bag." See Lewis' Abstract and Fig. 13 reproduced below.



Lewis' bellows-mechanical structure works by expanding the collapsed bag (see Fig. 11) so as to provide an expanded bag (see Fig. 10) thereby creating a negative pressure.



Importantly, the Examiner's attention is directed to Lewis' disclosure at column 5, lines 7ff, which, in pertinent part, recites:

Before effecting the connection at **50**, the collapsible bag is fully collapsed by moving the moveable plate member towards the fixed plate member, thereby completely collapsing the bag, and expelling air therefrom. With the bag held in the collapsed configuration, the tubing connection at the check valve assembly is effected, whereupon the plate members are then permitted to be detracted from one another by the biasing means. This action produces a reduced pressure within the entire system, including the closed wound itself.

Therefore, with reference to Lewis' Fig. 13, this system works by, for example, springs pushing apart two plates, between which is a bellows-type arrangement. An apertured end portion **51** is placed inside a wound of a patient, thereby creating a closed system. The bellows-mechanical system expands, by way of the springs pulling the plates apart, and results in a negative pressure, thereby pulling any secretions at the needle into the bellows system. However, the bellows system is not pre-evacuated before the needle **51** is placed inside the wound. Therefore, Lewis does not disclose a pre-evacuated chamber, as required by claim 1. In other words, Lewis does not disclose a closed drainage device with all of the features alleged by the Office because Lewis' bellows-mechanical system **does not include a pre-evacuated chamber**.

Moreover, Lewis' bellows-mechanical system works by a different principle when compared to the claimed closed drainage device. For instance, it is impossible to pre-evacuate Lewis' collapsible bag because the act of pre-evacuation necessarily *would lead to a collapsed bag* without any substantial capacity to withdraw fluid from a patient in need thereof. Because the principle of operation of Lewis is different from the claimed closed drainage device, Applicant believes that the application of Lewis (either alone or in combination with any one of

the cited secondary references) does not render the claimed closed drainage device obvious. (*See* MPEP § 2143.01 (VI).)<sup>1</sup>

The Office has relied on the secondary references of Broadnax, Gilcher, Olausen, Hogan, Dennehey, Friend, and Trace, for secondary features. Applicant believes that none of these secondary references rectify Lewis' deficiency.

Applicant wishes to point out that Lewis relates to a "continuous suction apparatus," which is similar to the known existing devices, as stated on page 1, lines 21-26 of the specification. These systems are suitable "for the continuous removal of drainage fluid over a relatively long post-operative period of time. Such a drainage device needs to be secured to the patient, and is not suitable for the removal of serous fluid over a short period of time." See also page 8, lines 14-20 of the specification, which states:

It is also envisaged that the closed drainage device will be used, in conjunction with long term drainage devices. In particular, in the event when a long term drainage device has been secured to the patient for a long term drainage of fluid and, once such a drainage device has been removed from the patient, a smaller amount of fluid continues to accumulate in the body cavity. It is envisaged that the drainage device of the present invention will be used to drain such fluid.

Applicant also notes that Lewis' bellows-mechanical system is bulky and requires use of a mechanical device that has special storage and maintenance requirements that are different from the claimed close drainage device. Applicant notes that the claimed close drainage device has certain advantages over the convention continuous suction apparatus, as noted at page 2, lines 13-20, which include but are not limited to: suitable for "quick removal of [accumulated] fluid," "quick and easy to use," and "a less bulky alternative to previous devices, so that it can be stored more efficiently and is less costly."

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<sup>1</sup> MPEP § 2143.01 (VI) states the following: "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)." Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.

Therefore, Applicant believes that rejections based on Lewis (either alone or in combination with any one of the cited secondary references) is improper and should be withdrawn. Acknowledgment of the same is respectfully requested.

Applicant concurrently files with the present response a Request for a Two-Month Extension of Time under 37 CFR § 1.136(a) with an authorization to charge any requisite fee to Applicant's representative Deposit Account No. 13-2725.

In view of the above remarks and amendments, Applicant believes that the present application is now in a condition for allowance. Applicant kindly requests that the Examiner acknowledge the same and pass the present application to issue. In the event that the Examiner discovers an informal matter that can be discussed by telephone, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below in order to expedite prosecution in the present application.



Respectfully submitted,  
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